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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,405	02/12/2004	Seogchan Kang	P06605US00	5865

27407 7590 07/28/2006

MCKEE, VOORHEES & SEASE, P.L.C.
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DES MOINES, IA 50309-2721

EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,405

Applicant(s)

KANG ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15, drawn to a method of identifying and selecting transformants comprising transforming a host cell with *Agrobacterium* carrying a vector containing a targeting construct, whereby recombination occurs, and selecting transformants, classified in class 435, subclass 471.
- II. Claims 16-20, 64 and 65, drawn to a strain of fungal cells transformed with a vector containing a targeting construct, and the vector, and *Agrobacterium* comprising the vector, classified in class 435, subclass 254.11, 252.2, 320.1.
- III. Claims 21-35, drawn to a method of identifying a gene knock out mutant comprising providing a polynucleotide construct, introducing into *Agrobacterium* the construct, incubating *Agrobacterium* produced with fungal cells under conditions so that the construct is integrated into a fungal cell genome wherein transformant resulting from knockout lack a negative selection marker, and ectopic heterologous or illegitimate transformants express both a negative and positive selection marker, selecting knockout mutants by subjecting transformed cells to a positive and a negative selection action, classified in class 435, subclass 471.

- III. Claim 36, drawn to a strain of transformed fungal cells comprising knockout mutations, classified in class 435, subclass 254.11.
- IV. Claims 37-52, drawn to a method of transforming fungal cells to identify mutants comprising inserting a polynucleotide construct into an Agrobacterium-based vector between T-DNA borders, introducing said vector into Agrobacterium tumefaciens, wherein said cells contain a virulence region, inducing [introducing?] virulence genes to T-DNA containing said construct from said Agrobacterium tumefaciens and incubating said Agrobacterium tumefaciens with a fungal cells to be transformed and selecting transformed cells from untransformed cells by subjecting transformants to a positive and a negative selection agent, classified in class 435, subclass 471.
- V. Claim 53, drawn to a strain of transformed fungal cells comprising T-DNA with virulence genes, classified in class 435, subclass 254.11.
- VI. Claims 54-58, drawn to a method of identifying and selecting transformants comprising transforming fungal cells with A. tumefaciens under conditions whereby recombination occurs, wherein transformants resulting from a gene knockout lack a negative selection marker and ectopic, heterologous or illegitimate transformants will express a negative and a positive selection marker, said A. tumefaciens comprising a gene disruption vector, said vector comprises a polynucleotide encoding a negative selection marker linked to a fragment of DNA flanked by DNA

sequence homologous to the polynucleotide to be targeted, wherein said fragment contains at least one mutant allele, wherein said mutant allele is generated by the insertion of a positive selection marker; regenerating transformants in the presence of both a positive and a negative selection agent, and selecting putative knockout mutants, classified in class 435, subclass 471.

- VI. Claims 59, drawn to a strain of transformed fungal cells with knockout mutations, classified in class 435, subclass 254.11.
- VII. Claims 60-61, drawn to a method of identifying and selecting transformants comprising transforming fungal cells with *A. tumefaciens* cells under conditions whereby recombination occurs wherein transformants resulting from gene knockout lack a negative selection marker, said vector comprising a pGreen II cloning site, a polynucleotide sequence that encodes a negative selection marker, said sequence is linked to a fragment of DNA, wherein said DNA fragment is disrupted by a positive selection marker; and selecting gene knockout mutants by subjecting transformed fungal cells to a positive and a negative selection agent, classified in class 435, subclass 471.
- VII. Claim 62, drawn to a polynucleotide having a DNA fragment disrupted by a positive selectable marker in a targeted polynucleotide, classified in class 536, subclass 23.1.

VIII. Claims 63, drawn to a polynucleotide comprising a first polynucleotide sequence encoding a negative selection marker; a DNA fragment disrupted by a positive selection marker, and a pGreen II cloning site, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different method, such as by transformation with isolated vector DNA.

Inventions of Group III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different method, such as by transformation with isolated vector DNA..

Inventions of Group V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially

different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different method, such as by transformation with isolated vector DNA..

Inventions of Group VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different method, such as by transformation with isolated vector DNA..

The products of Groups II, IV, VI, VIII, X, and XI are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups I, III, V, VII and IX are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, . The methods of Groups I, III, V, VII and XI comprise steps which are not

required for or present in the methods of the other groups: transforming a host cell cells with Agrobacterium comprising a vector comprising a fragment disrupted by a positive selection marker (I); introducing in Agrobacterium a polynucleotide construct (III); inserting a polynucleotide construct into an Agrobacterium-based vector between T-DNA borders (V); transforming fungal cells with A. tumefaciens comprising a vector comprising a fragment containing at least one mutant allele (VII); transforming fungal cells with A. tumefaciens comprising a vector comprising a fragment comprising a pGreen II cloning site. The end result of the methods are different: . Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Except for the specific relationships described above, the invention of Groups I-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups II, IV, VI, VIII, X and XI are not used in or made by the methods of Groups I, III, V, VII, IX (except for those relationships set forth above).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

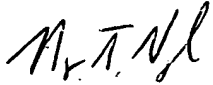
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
7/19/06


NANCY VOGEL
PRIMARY EXAMINER